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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,980	12/09/2003	George Chin-Sheng Chou	BHT/3092-397	2232

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03/02/2005

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FALLS CHURCH, VA 22041

EXAMINER

SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 03/02/2005.

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/729,980

Applicant(s)

CHOU ET AL.

Examiner

Rodney P. Swartz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20December2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 8-10 and 15-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 11-14 is/are rejected.
- 7) ☒ Claim(s) 1,2,11 and 13 is/are objected to.
- 8) ☒ Claim(s) 1-19 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 8-23-04 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

1. Applicants' Response to Restriction Requirement, received 20 December 2004, is acknowledged. Applicants elect, without traverse, Invention I, claims 1-7 and 11-14, drawn to method/kit to detect DNA, classified in class 435, subclass 6.

Claims 1-19 are pending. Claims 8-10 and 15-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

2. Claims 1-7 and 11-14 are under consideration.

Drawings

3. Figure 5 is objected to because it is unclear what is meant by "STANDAR" and "Smea". A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Abstract

4. The abstract of the disclosure is objected to because line 6, "is less" should be "to less". Correction is required. See MPEP § 608.01(b).

Specification

5. The disclosure is objected to because of the following informalities:

Page 3, lines 14 and 20, there should be a period after "M",

Page 4, lines 12, 19 and 20, there should be a period after "M"; line 18, "assay" should be "assays"

Page 5, line 14, "tube" should be "tubes"; "to magnetic" should be "to a magnetic",

Page 6, line 5, there should be "and" between effusion, throat,

Page 7, lines 24-26, there is no verb in the sentence,

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Page 8, lines 13-14, what is meant by "not limited but" in the sentence; lines 16, 17 and 19, "Wherein" should be "wherein"

Page 9, line 1, "to magnetic" should be "to a magnetic"; line 19, "products" should be "suppliers" or "producers",

Page 10, line 9, "3ml" should be "3ml,"; line 11, "450 μ l" should be "450 μ l,"

Page 12, line 9 "adding up" should be "adding",

Page 13, line 3 "adding up" should be "adding",

Page 14, line 12, "Wash" should be "wash",

Page 16, line 24, "varying" should be "various",

Appropriate correction is required.

Claim Objections

6. Claim 1 is objected to because of the following informalities: line 3, "in hybridization tube" should be either "in a hybridization tube" or "in hybridization tubes"; "probe linked" should be "probe is linked" and "to magnetic" should be "to a magnetic". Appropriate correction is required.

7. Claim 2 is objected to because of the following informalities: there is a] at the end of the claim which does not belong. Appropriate correction is required.

8. Claim 11 is objected to because of the following informalities: line 2, "to magnetic" should be "to a magnetic"; line 5, "nzyme" should be "enzyme". Appropriate correction is required.

9. Claim 13 is objected to because of the following informalities: line 8, "Wherein" should be "wherein". Appropriate correction is required.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claim 2 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 of copending Application No. 10/833,097.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims are drawn to a method of detecting *M. tuberculosis* DNA utilizing microorganism-specific probes in hybridization assays wherein said probes are linked to magnetic beads.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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13. Claim 1-7 are rejected under 35 U.S.C. 112, second paragraph, lack of antecedent basis for "tubes" in steps b and c. There is insufficient antecedent basis for this limitation in the claim because step (a) recites only one "tube".

Claims 2-7 depend from claim 1, but do not clarify the issue.

14. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 5 recite "suspending magnetic beads" in step (f). However, there is no recitation that these are the same as the magnetic bead which is linked to the probe. If the beads are the same, then it is recommended that Claims 1 and 5 recite "suspending said magnetic beads linked to the probe" in step (f).

Claims 2-4 and 6-7 depend from claim 1 but do not correct the indefiniteness.

15. Claims 11-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detection of microorganism DNA utilizing microorganism-specific probes, does not reasonably provide enablement for a kit for detecting microorganism cDNA comprising any/all other identified probes linked to magnetic bead. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of

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experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention – a kit for detecting microorganism cDNA comprising a probe linked to magnetic bead.

The state of the prior art is high for DNA hybridization when utilizing probes when can hybridize to a particular DNA. However, there is a lack of predictability thereof in the art to identify microorganism cDNA utilizing probes which are either non-microorganism DNA probes or probes of unidentified structure/function.

The amount of direction or guidance present in the instant specification indicates that identification of microorganism cDNA is possible if one utilizes microorganism-specific probes which actually hybridize to microorganism DNA.

The quantity of experimentation necessary to determine if any nonmicroorganism-specific probe will actually hybridize to microorganism cDNA for detection purposes constitutes merely an invitation to experiment without a reasonable expectation of success.

16. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: comparison of unknown tubes to a standard tube reaction.

The specification, page 15, recites specific levels of luminescence which determines a positive result. However, the instant claims are drawn to any level as being positive for detecting microorganism DNA because there is no determination/comparison to background luminescence or color change.

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17. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 recites "furocoumarin derivative", "angelicin derivatives", and "psoralen derivatives". The specification does not define the term "derivative", therefore the term is open-ended and indefinite.

Conclusion

18. No claims are allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

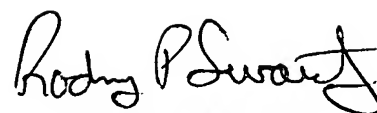
The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, reading "Rodney P. Swartz". The signature is fluid and cursive, with the first name "Rodney" and last name "Swartz" clearly legible.

RODNEY P. SWARTZ, PH.D.
PRIMARY EXAMINER

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February 28, 2005